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Requirements for the collection and transport of samples for medical laboratory examinations

Exigences pour le prélèvement et le transport d'échantillons à des fins d'examens en laboratoire médical

Reference number
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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

This first edition cancels and replaces ISO/TS 20658:2017, which has been technically revised.

The main changes are as follows:

— The Scope is now limited to activities occurring before samples are received by a laboratory for examination.

— The title has been changed to reflect a potentially wider audience than medical laboratories.

— This document is published as an International Standard rather than a Technical Specification.

— This document recognises that collection of samples can be provided by facilities independent of the medical laboratory.

— This document is closely aligned with ISO 15189 which is now included as a normative reference to this document.

— This document has been aligned with the mandatory ISO structure, which reflects its normative reference to ISO 15189.

— This document includes processes for emergency situations such as the COVID pandemic and indicates the possibility that samples may be collected in temporary or pop-up collection sites.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Medical laboratory services are essential to patient care and public health. A critical element of a medical laboratory service is the collection and transport of samples to a medical laboratory for testing.

These activities are collectively known as pre-examination processes, which also include receipt and handling of samples. Annex C provides an informative schematic of the pre-examination process.

This document provides the requirements for all activities related to collection and transport of samples to ensure the quality of medical laboratory examination results and to achieve better health outcomes for patients.

Receipt and handling of samples are deemed laboratory functions and covered in ISO 15189.

Collection and transport of medical laboratory samples can be undertaken in many different scenarios, some examples are described below:

— hospital in-patient collection;

— out-patient collection;

— home collection at the site of the patient;

— patient self-collection;

— physician office/clinic collection;

— pop-up/temporary and mobile collection sites.

Whatever the scenario, this document identifies the requirements to be followed to minimise poor patient outcomes.

In emergency situations, such as the response to the COVID-19 pandemic, temporary collection facilities were established in various jurisdictions with the aim of providing more access to collection services. This enabled more testing for COVID to occur. Temporary collection facilities may not be able to meet all of the requirements in this document, however, as far as possible they should conform to this document in order to reduce potential risks to patients. Local jurisdictions can provide further guidance on minimum best practice for sample collection and transport in these sorts of temporary facilities.

It has been well documented that unless the pre-examination processes of a medical laboratory are performed accurately, a significant risk to patient safety and poor patient outcomes can result.

The primary consideration is always the welfare of patients. This document has been developed with the objective of promoting the welfare of patients through confidence in the quality and competence of those collecting and transporting samples to medical laboratories.

The responsibility for the sample collection and transport of samples lies with the facility/person directly performing those activities. However, the medical laboratory performing the examination should clearly define its responsibility in the process including where collection and transport is outside of either its direct control or responsibility, or both.

Requirements for the collection and transport of samples for medical laboratory examinations

1 Scope

This document specifies requirements and good practice recommendations for the collection and transport of samples intended for medical laboratory examinations.

This document is applicable to medical laboratories and service providers, which can be independent from the medical laboratory, involved in laboratory pre-examination processes that include the examination request, patient preparation and identification, sample collection and transport. It can also be applicable to some biobanks.

This document does not apply to blood and blood products intended for transfusion, e.g. red blood cells, platelets, fresh frozen plasma, but can cover the collection and transport of donor samples for testing.

NOTE International, national or regional regulations or requirements can also apply to specific topics covered in this document.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 15189:2022, *Medical laboratories — Requirements for quality and competence*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 15189 the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
arterial puncture
procedure (3.15) that involves the collection of blood from arteries by puncturing the skin

3.2
biobank
legal entity or part of a legal entity that performs *biobanking* (3.3)

Note 1 to entry: A biobank encompasses personnel, facilities and procedures (e.g. management systems) and includes service providers, as well as repositories of biological materials.

[SOURCE: ISO 20387:2018, 3.5, modified — Note 1 to entry added.]